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IS 9408 (1986): Retractor, Self Retaining [MHD 7: Neurosurgery Instruments Implants and Accessories]

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UDC 615·472·5 : 616·8 — 089·853-72

IS : 9408 - 1986

Indian Standard

(Reaffirmed 1992)

SPECIFICATION FOR RETRACTOR, SELF RETAINING

(First Revision)

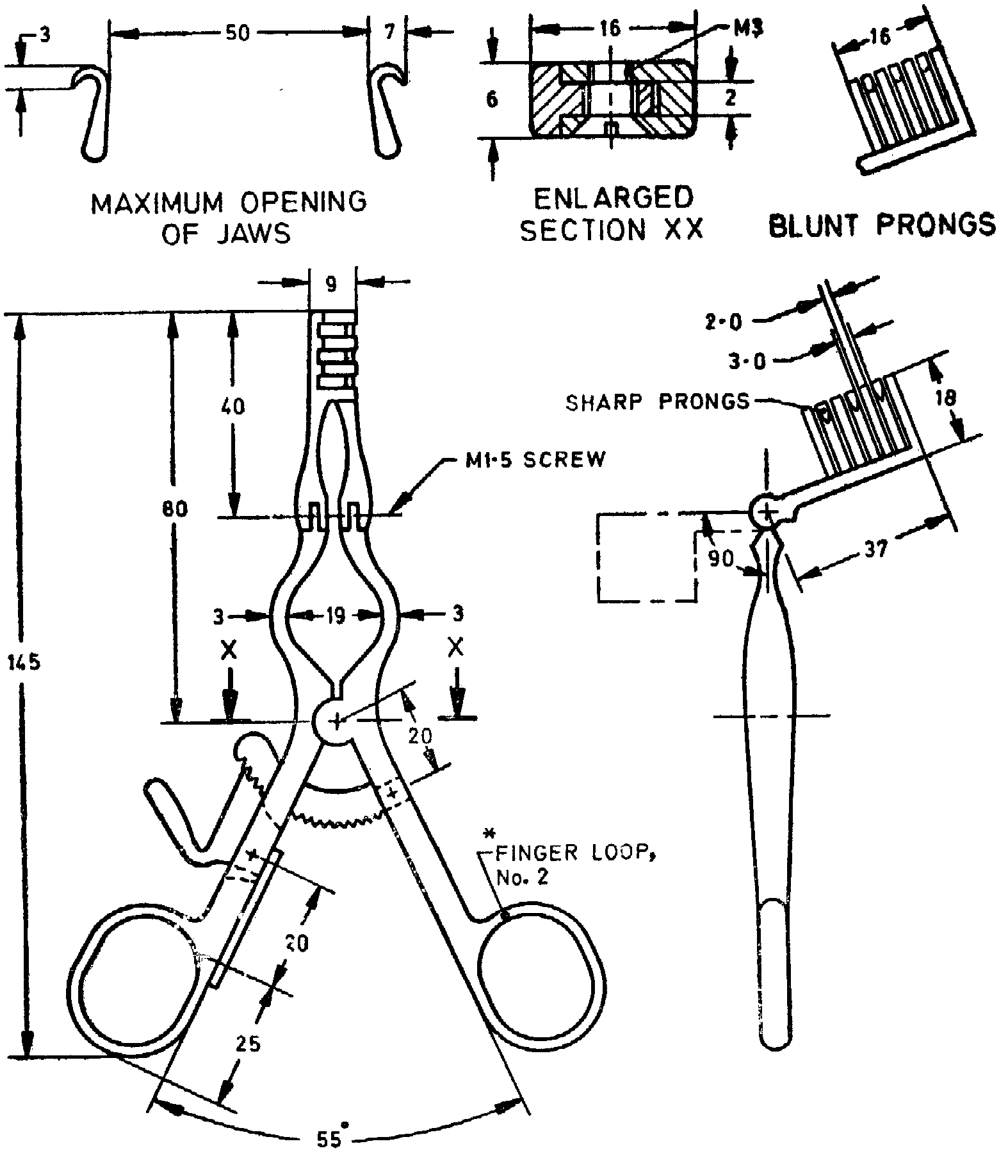
1. Scope — This Standard specifies material, dimensions and other requirements for selfretaining retractor used in neurosurgery.

2. Types — The self-retaining retractor shall be of the following types:

a) with hinged arms and sharp prongs,
b) with hinged arms and blunt prongs.

3. Shape and Dimensions — As shown in Fig. 1.

Neurosurgery Instruments Sectional Committee, CPDC 29 [Ref : Doc : CPDC 29 (1617)]



*See IS : 3642-1978 General requirements for surgical instruments (*first revision*).

All dimensions in millimetres.

FIG. 1 RETRACTOR, SELF RETAINING

Adopted 24 June 1986	© January 1987, ISI	Gr 2

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3.1 Tolerances on various dimensions shall be permitted as given below:

a) ±0·2 mm on dimensions up to 5·0 mm,
b) ±0·5 mm on dimensions above 5·0 mm and up to 10·0 mm,
c) ±1·0 mm on dimensions above 10·0 mm and up to 20·0 mm,
d) ±1·5 mm on dimensions above 20·0 mm and up to 100·0 mm, and
e) ±2·0 mm on dimensions above 100·0 mm.

4. Material — Stainless steel conforming to designation 20Cr13 or 30Cr13 of IS : 6603-1972 'Specification for stainless steel bars and flats'.

5. Workmanship and Finish

5.1 All the surfaces, except the ratchet teeth, shall be smooth and free from pits, burrs, cracks and other surface defects.

5.2 The edges of the retractor prongs shall taper to a sharp point and a blunt point for type (a) and type (b) retractors respectively. All the other edges shall be even and rounded.

5.3 The retractor arms shall open and close smoothly without any friction or undue resistance or play at the joint.

5.4 The ratchet teeth shall conform to **8** of IS : 3642-1978 'General requirements for surgical instruments (*first revision*)'.

5.5 The joint shall be box type and shall conform to **6** of IS : 3642-1978.

5.6 The finger loops shall be No. 2 conforming to **12** of IS : 3642-1978.

5.7 The spring meant for control of finger rest shall be reasonably stiff. The ratchet arm with the finger rest pressed shall swivel freely.

5.8 The retractor shall be finished smooth, polished bright and passivated.

5.8.1 The retractor shall be passivated by treating it with 10 percent (*v/v*) nitric acid solution for not less than 30 minutes at a temperature of not less than 10°C and not exceeding 60°C. The retractor shall then be rinsed in water, dried in hot air and the joint lightly lubricated with a non-toxic and non-corrosive substance.

6. Heat Treatment — The retractor, except the spring, shall be hardened and tempered to a hardness of 390 to 475 *HV*. The spring shall be hardened and tempered to a hardness of 420 to 475 *HV*. The hardness shall be tested in accordance with IS : 1501 (Part 1)-1984 'Method for Vickers hardness test for metallic materials: Part 1 *HV* 5 to *HV* 100 (*second revision*)'.

7. Tests

7.1 The arms of the retractor shall be opened by about 50 mm width measured at its tip. The retractor shall be gripped at the retracting blades and a compressive force of 100 N (10 kgf approximately) shall be applied for two minutes trying to close the jaws. The ratchet shall not slip under the force and shall show no sign of damage on removing the force. The test shall be repeated with two different arm openings.

7.2 *Corrosion Resistance* — The retractor shall be subjected to boiling and autoclaving test in accordance with IS : 7531-1975 'Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments'. It shall show no sign of corrosion after the test.

8. Marking — Each retractor shall be legibly marked by etching or stamping with the manufacturer's name, initials or registered trade-mark, the country of manufacture and the words 'Stainless Steel'.

8.1 *ISI Certification Marking* — Details available with the Indian Standards Institution.

9. Packing — Each retractor shall be wrapped in a moisture-proof paper or put in a polyethylene bag and then individually packed in a cardboard carton. Alternatively, the retractor may be packed as agreed to between the purchaser and the supplier.

10. Sampling — Sampling procedure and acceptance criteria for conformity shall be as agreed to between the purchaser and the supplier. A recommended scheme sampling is given in Appendix A.

APPENDIX A

(*Clause* 10)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY

A-1. LOT

A-1.1 In a consignment, all the retractors of the same pattern and dimensions shall be grouped together to constitute a lot, not exceeding 50 items. Each lot shall be tested for the requirements of this specification.

A-2. SCALE OF SAMPLING AND CRITERIA FOR CONFORMITY

A-2.1 Eight retractors shall be selected at random from each lot by using random number tables (IS : 4905-1968 Methods for random sampling). Each retractor in the sample shall be individually tested for the requirements of shape and dimensions (**3**) material (**4**) workmanship and finish (**5**) and marking (**8**). Any retractor failing to meet one or more of the above requirements shall be termed defective. No defective retractor in the sample shall be permitted if the lot is to be accepted in this clause.

A-2.2 The lot which has been found satisfactory as per **A-2.1** shall be tested for hardness (**6**), flexibility (**7.1**) and corrosion resistance test (**7.2**). For this purpose, one retractor shall be sampled at random and be tested for the above requirements. If need be, more retractors may be drawn for conducting the relevant tests.

A-2.2.1 No failure shall occur if the lot is to be declared acceptable under this clause.

EXPLANATORY NOTE

This standard was first published in 1980. The standard has been revised to incorporate additional requirements, like tolerances on various dimensions, method of passivation and sampling scheme. Details of Retractors with unhinged arms have been deleted as they are not widely used now.

Printed at New India Printing Press, Khurja, India